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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,836	10/03/2003	Manoussos Perros	PC10925B	1139

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AGOURON PHARMACEUTICALS, INC.  
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EXAMINER

HUANG, EVELYN MEI

ART UNIT PAPER NUMBER

1625

DATE MAILED: 07/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/678,836

Applicant(s)

PERROS ET AL

Examiner

Evelyn Huang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 38-45 is/are pending in the application.
- 4a) Of the above claim(s) 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/865,950.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 38-45 are pending. Claims 1-37 have been canceled according to the preliminary amendment filed on 10-3-2003.

#### ***Priority***

2. In US 20020013337, which is the published application of 09/865950, now US Patent No. 6667314, and in the Cross Reference to Related Applications of US Patent No. 6667314, the foreign priority UK 0014046.7, filed on 5-26-2000 is recited. The instant application therefore is a continuation of 09/865950 entitled to the priority of the two GB applications and the two US provisional applications.

#### ***Election/Restrictions***

3. Newly submitted claim 45 is directed to an invention that is independent or distinct from the invention originally claimed in claims 38-44 for the following reasons:

The patentability of the composition comprising the compound of formula I and additional therapeutic agents as recited in claim 45 depends on the type and amount of the multiple active ingredients, their interaction, co-action, e.g. synergism etc., which is patentably distinct from the composition containing only compound of formula I as a single active ingredient and the method of using the compound of formula I of claims 38-44.

Since applicant has received an action on the merits for the originally presented invention of claims 38-44, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 45 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 112(2)***

4. The rejection for Claims 40, 44 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because the amendment has obviated the rejection.

***Claim Rejections - 35 USC § 112(1)***

5. The rejection for Claims 38, 44 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn upon reconsideration in view of the amendment amending the method to antagonizing the CCR5 receptor and applicants' remarks.

***Claim Rejections - 35 USC § 112***

6. The enablement rejection under 35 U.S.C. 112, first paragraph, is withdrawn for claims 41-42 upon reconsideration in view of the references submitted with the response and applicants' remarks. The abstract from the September 2003 ICAAC conference discloses that UK-427857, (Examples 4, 6, 7 of the instant), exhibits antiviral effects in HIV-infected patients. This compound is also currently in Phase III clinical trials for the treatment of HIV infection.

The enablement rejection, however, is maintained for claims 38-40, 43, 44 for reasons of record.

The amended claim 38 is directed to a mechanism of antagonizing a CCR5 receptor in a mammal. The claims as recited, however, embrace any degree of antagonizing the CCR5 receptor which may or may not be linked to the treatment of diseases associated with the CCR5 receptor, the scope of the claims is therefore not commensurate with that of the objective enablement, especially in view of the absence of a full written description of the as yet unidentified CCR5-receptor-associated responses/conditions/activities/disorders which the recited mechanism reaches out to. One of ordinary skill in the art therefore would not be able to use the inventive compound as claimed without undue experimentation.

Although CCR5 antagonist has been shown for the treatment of HIV infection, the use of a CCR5 antagonist for treating all the diseases recited in claims 39-40, 43, 44 has not been described. At the time of the invention, there is no umbrella drug known to treat all these diverse diseases as recited in the claims. In view of the high degree of unpredictability in the chemokine art, the limited working examples, and the breadth of the claims does not commensurate with the scope of the objective enablement, one of ordinary skill in the art would not be able to use the invention as claimed without undue experimentation.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. It is unclear whether claims 39-44 are independent claims or dependent claims. If they were independent claims, the referencing to the compound of claim 38 would be improper, and the compound of formula I should be recited in these claims.

b. Claims 41, 42, for these method claims, the subject to whom the compound of Formula I is administered is missing but is required.

c. Claim 44, the term 'comprises' in 'antagonizing comprises' is open-ended and is therefore indefinite. Furthermore, the meaning of 'the CCR5-receptor associated responses' is unclear in that to what degree of association with the CCR5 receptor is required for the response to be considered 'the CCR5-receptor associated responses'. Do they refer to the responses upstream or downstream of the CCR5 receptor? A definition is not found in the specification.

***Allowable Subject Matter***

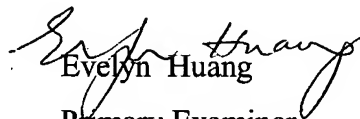
8. Claims 41, 42 would be allowable upon overcoming the 112 second paragraph rejection.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Evelyn Huang  
Primary Examiner  
Art Unit 1625